510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
#K041202

B. Purpose for Submission:
New Device

C. Analyte:
Fecal Occult Blood (FOB)

D. Type of Test:
Qualitative

E. Applicant:
WHPM, Inc.

F. Proprietary and Established Names:
Hemosure™ One-Step Fecal Occult Blood (FOB) Test; Occult Blood Test

G. Regulatory Information:

1. Regulation section:
   CFR Section 864.6550 – Occult Blood Test
2. Classification:
   Class II
3. Product Code:
   KHE
4. Panel:
   Hematology (81)

H. Intended Use:

1. Intended use(s):
   The Hemosure™ One-Step FOB Test is a rapid, immunochemical device for *in vitro* diagnostic use in qualitative determination of fecal occult blood by laboratories or physician's offices.
2. Indication(s) for use:
   Same as above; and it is useful to determine gastrointestinal (GI) bleeding found in a number of GI disorders, e.g., diverticulitis, colitis, polyps and colorectal cancer.
3. Special condition for use statement(s):
   N/A
4. Special instrument Requirements:
   N/A

I. Device Description:

The Hemosure™ One-Step FOB Test is a sandwich immunoassay; and employs a combination of monoclonal and polyclonal antibodies (MAB and PAB) to selectively identify human hemoglobin (hHb) in test samples with a high degree of sensitivity. It consists of a:

- Test Cassette, individually sealed in a foil pouch, containing a combination of mouse MAB and sheep or goat PAB, directed against human hemoglobin (hHb); and
- Fecal Collection Tube of extraction buffer, 2.0 mL.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Alfa Scientific Designs, Inc. Instant-View FOB (II) Test
2. Predicate K number(s):
   #K021423
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Test type	One-step sandwich immu - noassay	Same
Antibodies (poly-clonal and mono-clonal)	Anti-human hemoglobin; and goat anti-mouse IgG	Same
Sample type	Feces	Same
Sensitivity	50 ng hHb/mL	Same
Test window	5 – 10 minutes	Same
Format	Cassette	Same
Differences		
Item	**Device**	**Predicate**
Number of tests/kit	(1) test	(20) tests
Indicator color	Pink-rose	Burgundy

K. Standard/Guidance Document Referenced (if applicable):

N/A

L. Test Principle:

The test cassette consists of a pad containing mouse anti-hHb antibodies conjugated to colloidal gold; a nitrocellulose strip containing a test line (anti-hHb antibodies); and a control line of goat anti-mouse IgG antibodies. As the test sample flows or migrates, via capillary action, through the absorbent test strip, a labeled antibody-dye conjugate binds to human hemoglobin (hHb) in the specimen. An antibody-antigen complex forms, binds to the anti-hHb antibody in the positive test reaction zone, and produces a pink-rose color band for hHb ≥50 ng/mL. In the absence of hHb, no line is produces in the positive test reaction zone. The control line binds the conjugated mouse antibodies regardless of the hHb concentration. A pink-rose color in the control reaction zone demonstrates that the device and reagents are functioning correctly.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
    - *a. Precision/Reproducibility:*
      Samples (N=100) spiked with varying levels of hHb, ranging from 0 – 2000 ng/mL, were tested, at (3) sites, with (3) lots of tests. At the 50 ng hHb/mL cut-off, Lot 1 yielded (3) false (-) results; and Lots 2 and 3 yielded (1) false (-) result.
    - *b. Linearity/assay reportable range:*
      No prozone effect was seen up to 2000 ng hHb/mL
    - *c. Traceability (controls, calibrators, or method):*
      Mouse monoclonal and polyclonal anti-human hemoglobin antibodies
    - *d. Detection limit:*
      A limit of 50 ng hHb/mL buffer or 50 ug hHb/g feces was determined using samples (N=50), spiked with levels of hHb that ranged 0 2000 ng hHb/ml. They were tested in-house with the proposed and predicate devices. There was agreement of > 99%.
    - *e. Analytical specificity:*
      Interference testing was performed on aqueous samples with and without 50 ng hHb/mL. Substances tested included aqueous extracts of fruits and vegetables; 20 mg/mL solution of horseradish perioxidase; and toilet water with cleaner and deodorizer. Cross reactivity was tested on (9) species of animal hemoglobins, using diluted human fecal samples. No false results were obtained.
    - *f. Assay cut-off:*
      50 ng hHb/mL buffer
2. Comparison studies:
    - *a. Method comparison with predicate device:*
      Three lots of the Hemosure and (1) lot of the Alfa assay were tested, in-house, on fecal samples (N=50) spiked with hHb to 1, 37.5, 50, 62.5 and 2000 ng hHb/mL. Both devices gave 30 (+) and 20 (-) readings for > 99% agreement.

b. Matrix comparison:
N/A

3. Clinical studies:
   a. Clinical sensitivity:
   N/A
   b. Clinical specificity:
   N/A
   c. Other clinical supportive data (when a and b are not applicable):
   The study on samples (N=100) tested in-house, was also performed at (2) independent sites: a POL and a reference lab. The blinded study used (3) test lots. Stool samples were spiked with hHb at 1, 37.5, 50, 62.5 and 2000 ng hHb/mL. Percent (%) agreement ranged from 95 - > 99%, for an overall agreement of 98%.
4. Clinical cut-off:
   N/A
5. Expected values/Reference range:
   Negative (<50 ug hHb/g feces)

N. Conclusion:

The submitted material in this premarket notification is complete and supports a substantial equivalence decision.